

REMARKS

Claims 1-3, 5, 8 and 10-12 are pending in this application.

Reconsideration and allowance of the claims are respectfully requested in view of the following remarks.

I. Rejection Under 35 U.S.C. §112

The Office Action rejects claim 12 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically the Office Action, at pages 2-3, alleges that the recitation of, "reacting a mixture consisting of diglycerin with isostearic acid, and then reacting the obtained ester compound with dimer acid," is not adequately disclosed by the application as originally filed. Applicants respectfully disagree.

For at least the reasons presented below, it is respectfully asserted that one skilled in the art would have recognized, in the specification as filed, that Applicants were in possession of the subject matter set forth in claim 12. Accordingly, the addition of claim 12 in the August 9, 2010 Amendment does not constitute new matter.

To provide written description for a claim, the specification as originally filed must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventors were in possession of the invention as claimed. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Therefore, the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would have not recognized in the specification a description of the invention defined by the claims. See *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

The specification recites, "In the present invention, diglycerin and isostearic acid are selected from various known raw materials for ester compounds and reacted in the predetermined order and in the predetermined amounts to successfully obtain the hydroxyl compound with an appropriate hydroxyl value" (*see* specification, paragraph [0020]). The specification further recites, "The hydroxyl compound of the present invention is prepared in a two-step process comprising a first step wherein diglycerin is reacted with isostearic acid, and a second step wherein the ester compound thus obtained is reacted with dimer acid. In the first step, isostearic acid binds preferentially to the hydroxyl group at position 1, primary hydroxyl group, of the diglycerin due to the reactivity difference among the hydroxyl groups of the diglycerin. Accordingly, the obtained mono-ester and di-ester are esterified more at position 1 of the diglycerin. Upon further esterifying these with dimer acid, more hydroxyl compound has a coupled structure wherein the dimer acid binds to the remaining hydroxyl group at position 2, secondary hydroxyl group" (*see* specification, paragraph [0024]) (*see also* paragraphs [0001], [0018] and [0035]).

Furthermore, the specification also recites, "An example of the two-step process is as follows: in the first step, diglycerin and isostearic acid are placed in a reactor and the temperature is raised gradually preferably to a temperature of from 100 to 250 degrees C, and more preferably from 180 to 240 degrees C while distilling off the produced water. The reaction mixture is retained at the temperature until no water is distilled off any more. The retention time is preferably 2 to 50 hours, more preferably 3 to 40 hours, and further more preferably 4 to 30 hours. In the second step, the ester compound obtained in the first step and dimer acid are placed in a reactor and, then, reacted under the same conditions as in the first step. In the first step, the reaction is performed so that the hydroxyl value of the ester of diglycerin with isostearic acid is preferably 150 to 330. In actual operations, an acid value of the ester compound is monitored and adjusted preferably to at most 5.0, more preferably at

most 3.0. The acid value can be determined accurately in a shorter time, so that reaction is controlled more easily with the acid value. The acid value is determined according to the Cosmetics Raw Material Standards. By controlling the hydroxyl or acid value in this way, it is possible to easily control the viscosity and the hydroxyl value of the desired hydroxyl compound in the reaction of the ester compound obtained in the first step with a predetermined amount of dimer acid in the second step" (*see* specification, paragraph [0024]).

At least these portions of the specification as originally filed support the recitation of "the hydroxyl compound is obtained by reacting a mixture consisting of diglycerin with isostearic acid, and then reacting the obtained ester compound with dimer acid." One of ordinary skill in the art would have recognized, in the application as filed, that the cosmetic, as specified in claim 1, can be obtained, for example, in the manner described in paragraph [0024] of the specification.

Therefore, it is respectfully asserted that the Examiner has not met his initial burden of showing, by a preponderance of evidence, why a person skilled in the art would not have recognized in the specification as filed a description of the invention defined by claim 12. See MPEP §2163(III)(A). The Office Action (Patent Office) merely states that the allegation of new matter "is evidenced by the instant specification wherein it is stated that commercially available diglycerines can be utilized, for instance, 'Diglycerol', trademark, from Solvay" (Office Action, page 3, lines 1-3). The Office Action further asserts that the Product Data Sheet from Solvay Chemicals International (already of record in this application) states that its "Diglycerol" product has a minimum of 90% diglycerol, and the remainder being a combination of glycerol and triglycerol. As a result, the Office Action asserts that "Diglycerol" from Solvay Chemicals International may not be diglycerol.

However, it is respectfully asserted that one ordinarily skilled in the chemical arts would know that it is rare, if not impossible, for raw materials to have 100% purity, especially

materials in the glycerin family of chemicals. Instead, one of ordinary skill would have known that impurities may be present due to the production process, or to difficulties in achieving complete separation. Namely, in the production of diglycerin (*e.g.*, product "Diglycerol"), it is remarkably difficult to remove glycerin, triglycerin and other impurities from diglycerin due to strong similarities in chemical and physical properties between these compounds.

"Diglycerin 801," the diglycerin used in the Declaration submitted with the Amendment filed on August 9, 2010, contains 94.6 wt.% diglycerin, 2.0 wt.% triglycerin, 0.7 wt.% glycerin and trace amounts of other materials, as evidenced in Gas Chromatography chart 1, attached hereto. Likewise, "Diglycerol" of Solvay Chemicals International contains 93.3 wt.% diglycerin, 2.4 wt.% triglycerin, 0.2 wt.% glycerin and trace amounts of other materials, as shown in Gas Chromatography chart 2, attached hereto. One of ordinary skill would have understood that both "Diglycerin 801" and "Diglycerol" represent diglycerol in the relevant art. One of ordinary skill in the art, at the time of invention, would have been aware that compositions with such high amounts of diglycerin would have been considered diglycerin.

In view of the above, the specification as filed clearly discloses a cosmetic according to claim 1, wherein the hydroxyl compound is obtained by reacting a mixture consisting of diglycerin with isostearic acid, and then reacting the obtained ester compound with dimer acid. One of ordinary skill in the art would have clearly envisioned that Applicants were in possession of this subject matter of claim 12 at the time the application was filed. Should the Examiner disagree, the Examiner is respectfully requested to articulate, by a preponderance of evidence, why a person skilled in the art would not have recognized in the specification a description of the subject matter set forth in claim 12.

Based on the above, one of ordinary skill in the art, having read the specification, would have recognized that Applicants were in possession of the features recited in claim 12

at the time of filing the application. Thus, claim 12 complies with the written description requirement of 35 U.S.C. §112, first paragraph.

Accordingly, reconsideration and withdrawal the rejection are respectfully requested.

II. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1-3, 5, 8 and 10-12 under 35 U.S.C. §103(a) over U.S. Patent No. 6,242,499 ("Gruning"). This rejection is respectfully traversed.

The above discussion with respect to the rejection under 35 U.S.C. §112, first paragraph, applies to this rejection.

Gruning discloses polyglycerols obtained "from epichlorohydrin or glycidol" (Gruning, col. 3, lines 23-24). The polyglycerols of Gruning have the following oligomer distribution:

Glycerol	0 to 30% by weight
Diglycerol	15 to 40% by weight
Triglycerol	10 to 55% by weight
Tetraglycerol	2 to 25% by weight
Pentaglycerol and higher components	0 to 15% by weight

(Gruning, col. 3, lines 25-32). Accordingly, the polyglycerol compositions disclosed by Gruning have a significant oligomer distribution and, at best, are a mixture of various glycerol compounds and would be recognized as such by one of ordinary skill in the art.

More specifically, Gruning discloses polyglycerols having the oligomer distribution as listed above, where triglycerol and tetraglycerol are two necessary components in the polyglycerol of Gruning (Gruning, col. 3, lines 25-32). Thus, Gruning does not disclose a cosmetic comprising a hydroxyl compound obtained by reacting diglycerin with isostearic acid, wherein a molar ratio among diglycerin, isostearic acid, and dimer acid is 1.0 : 1.4 to 1.6 : 0.5 to 0.8, as recited in claims 1 and 11. Gruning further fails to provide any reason or rationale for one of ordinary skill in the art to have removed triglycerol, tetraglycerol, glycerol

and any pentaglycerols and higher from Gruning's polyglycerol and, in effect, to have replaced the oligomer distribution of Gruning with diglycerol, to have obtained the claimed molar ratio among diglycerin, isostearic acid, and dimer acid.

In support that the composition of claims 1 and 11 would not have been rendered obvious by Gruning, a Declaration Under 37 C.F.R. §1.132 of Naoki Sasaki and Mari Yoshida (“Declaration”) showing the advantageous and unexpected results of the composition of claims 1 and 11 was submitted with the Amendment filed on August 9, 2010.

As described in the Declaration, experimental tests were conducted on three compositions: (1) HAILUCENT, an Example according to Preparation Example 3 of the specification; (2) Lot 100407, a Comparative Example that is representative of Gruning; and (3) ISOLAN® PDI, a Comparative Commercial Example of Gruning. The compositions are summarized in Table 1 on the following page.

Table 1
Experimental Compositions

	COMPOSITION	DESCRIPTION
1	<p align="center">HAILUCENT</p> <p align="center">Example according to Preparation Example 3 of the Specification</p>	<p>HAILUCENT is a product of Kokyu Alcohol Kogyo Co., Ltd</p> <p>HAILUCENT was prepared in a manner identical to Preparation Example 3 of the present specification, except that the diglycerol used was “Diglycerin 801” ex. Sakamoto Yakuhin Kogyo Co., Ltd., instead of K COL II (see specification, paragraphs [0035] and [0036]).</p> <p>Diglycerin 801 is equivalent to K COL II and was used because K COL II is no longer being produced (see specification, paragraph [0023]).</p> <p>The isostearic acid, “isostearic acid EX”, used in “HAILUCENT” is a purified one from Prisoline 3507, ex. Unichema; and the dimer acid, “PRIPOL1009”, used in “HAILUCENT, has an average degree of polymerization of 2.0 (almost pure).</p> <p>The mole ratio of diglycerin : isostearic acid : dimer acid in “HAILUCENT” is 1: 1.5: 0.65.</p>
2	<p align="center">Lot 100407</p> <p align="center">Comparative Example of Gruning</p>	<p align="center"><i>Please see Declaration for synthesis of Lot 100407</i></p>
3	<p align="center">ISOLAN® PDI</p> <p align="center">Comparative Commercial Example of Gruning</p>	<p>ISOLAN® PDI is a product of Goldschmidt AG, the assignee of Gruning (U.S. Patent No. 6,242,499).</p> <p>The term “ISOLAN® PD1” is the trade name for the INCI/CTFA name: diisostearoyl polyglyceryl-3 dimer dilinoleate.¹</p>

¹ see, e.g. http://www.manufacturingchemist.com/company/single_company/Evonik_Goldschmidt_GmbH/46023 (last visited: 15 May 2010).

The number average molecular weight and viscosity at 60°C were measured for each composition. Additionally, five panelists evaluated the compositions' removal with water. Gloss properties were also measured for each of the three compositions.

The results are summarized in Table 2 as show below.

Table 2

Number Average Molecular Weight, Viscosity, Removal with Water and Gloss

Experimental Composition	Number average molecular weight	Viscosity at 60°C; [mPa.s]	Removal with Water	Gloss
HAILUCENT Example According Preparation Example 3 of the Specification	4936	2940	“strong remain” by all of the five panelists	79
Lot 100407 Comparative Example of Gruning	2927	909	“no remain” by all of the five panelists	70
ISOLAN® PDI Comparative Commercial Example of Gruning	2856	900	“no remain” by all of the five panelists	68

As shown above in Table 2, the viscosity of HAILUCENT is **223.4% greater** than the viscosity of Lot 100407, the Comparative Example of Gruning, and **226.7% greater** than ISOLAN® PDI, the commercial embodiment of Gruning. The gloss of HAILUCENT is also **12.8% greater** than the gloss of Lot 100407, and **16.1% greater** than ISOLAN® PDI. In addition, HAILUCENT also performed superior with respect to the removal with water test

conducted by five panelists, yielding a "strong remain" of the composition from all five panelists, as shown above. The sizeable difference with respect to viscosity, gloss and improvement in removal with water that was achieved as a result of selecting diglycerin, as recited in claims 1 and 11, over other higher and lower order glycerol components was unexpected from similar compositions that were prepared with a polyglycerol comprised of triglycerol and tetraglycerol, glycerol pentaglycerols and higher.

Gruning provides no reason or rationale for one of ordinary skill in the art to have modified the reference in the manner necessary to have obtained the composition recited in claims 1 and 11 with any reasonable expectation of success.

Based on the above, Gruning would not have rendered claims 1 and 11 obvious. The remaining claims variously depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable, as well as for the additional features recited therein.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-3, 5, 8 and 10-12 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Sarah Lhymn
Registration No. 65,041

WPB:SQL/hs

Attachments:

Gas Chromatography Chart 1 ("Diglycerin 801")
Gas Chromatography Chart 2 ("Diglycerol" from Solvay Chemicals International)
Petition for Extension of Time

Date: February 15, 2011

OLIFF & BERRIDGE, PLC
P.O. Box 320850
Alexandria, Virginia 22320-4850
Telephone: (703) 836-6400

<p>DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry of this filing; Charge any fee due to our Deposit Account No. 15-0461</p>

2011年 2月10日 18時21分

MATSUI & ASSOCIATES

NO. 3309 P. 4/5

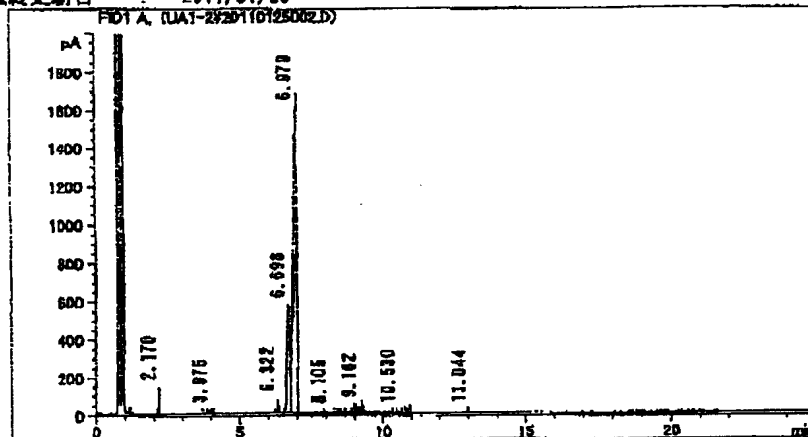
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サンプル名 : ジグ リセリン BD1

chart 1

注入日 : Tue, 25. Jan. 2011
サンプル名 : ジグ リセリン BD1
測定ロット : 90204-2
分析メソッド : C:\CHEM32\1\METHODS\UA1-2.M
解析メソッド : C:\CHEM32\1\METHODS\UA1-2.M

Our raw material

最終更新日 : 2011/01/25



面積パーセントレポート

ピーク	RT [min]	ピークタイプ	高さ	面積 [pA*s]	面積 [%]	化合物名	算出値 (%)
1	2.170	BB	127.77	153.16	0.87	グリセリン	0.69%
2	3.828	BY	8.74	10.69	0.06	glycerin	
3	3.900	VY	8.30	12.26	0.07		
4	3.975	VY	4.56	7.19	0.04		
5	4.051	VY	8.02	17.24	0.10		
6	4.131	VY	8.90	16.90	0.10		
7	6.322	VB	68.49	205.62	1.17	ジグリセリン	94.63%
8	6.698	BY	557.84	4059.72	23.06	diglycerin	
9	6.979	VY	1588.57	12341.84	70.10		
10	8.105	VY	0.93	5.63	0.03		
11	8.305	VB	5.65	9.34	0.05		
12	8.448	BY	3.34	6.52	0.04		
13	8.618	VY	3.24	11.58	0.07		
14	8.831	VY	5.77	22.37	0.13		
15	8.974	VY	50.84	187.14	1.06		
16	9.162	VY	31.75	82.46	0.47		
17	9.253	VY	58.82	135.90	0.77		
18	9.326	VY	36.78	87.74	0.38		
19	10.417	BY	3.06	5.52	0.03	トリグリセリン	1.99%
20	10.530	VY	2.83	9.49	0.05	triglycerin	
21	10.734	VY	29.15	97.20	0.55		
22	10.906	VB	41.91	134.01	0.76		
23	13.044	VY	0.79	5.44	0.03		

Column : DB-1 15m X 0.25mm X 0.1um Film
OVEN : 100°C → 10/min → 320°C (5min hold)
INLET : 250°C, 1mL/min, (50:1)
DET : FID Temp : 280°C J:280°C

2011年 2月10日 18時22分

MATSUI & ASSOCIATES

NO. 3309 P. 5/5

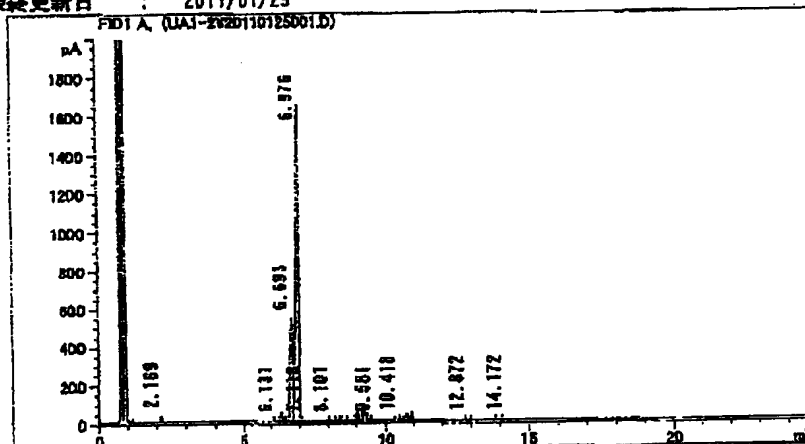
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サンプル名 : Diglycerol

chart 2

注入日 : Tue, 25. Jan. 2011
サンプル名 : Diglycerol
測定ロット : 211-013-8
分析メソッド : C:\CHEM32\1\METHODS\UA1-2.M
解析メソッド : C:\CHEM32\1\METHODS\UA1-2.M

"Solvey Diglycerol"

最終更新日 : 2011/01/25



面積パーセントレポート

ピーク	RT [min]	ピークタイプ	高さ	面積 [pA*s]	面積 [%]	化合物名	算出値 [%]
1	2.189	BB	27.92	35.57	0.21	グリセリン	0.17%
2	6.131	VV	1.65	5.49	0.03	グリセリン	
3	6.319	VV	49.97	148.92	0.87	グリセリン	
4	6.693	VV	535.62	3680.15	21.44	グリセリン	93.28%
5	6.976	VV	1517.45	12111.17	70.57	diglycerol	
6	7.118	VB	0.59	5.43	0.03		
7	8.101	VV	0.98	5.20	0.03		
8	8.305	VB	5.19	8.77	0.05		
9	8.447	BB	3.05	5.16	0.04		
10	8.613	VV	3.15	12.04	0.07		
11	8.832	VV	7.83	27.89	0.16		
12	8.980	VV	82.11	173.80	1.01		
13	9.039	VV	82.34	158.10	0.92		
14	9.168	VV	56.26	131.33	0.77		
15	9.259	VV	92.39	317.71	1.85		
16	9.581	VV	1.38	5.59	0.03		
17	10.418	VV	3.36	6.29	0.04		
18	10.532	VV	3.57	11.88	0.07	トリステリン	2.41%
19	10.736	VV	37.56	120.91	0.70	トリステリン	
20	10.909	VV	47.26	154.95	0.90	トリステリン	
21	12.872	VV	1.06	6.68	0.04		
22	13.043	VV	1.63	11.58	0.07		
23	13.978	VV	2.03	10.25	0.06		
24	14.172	VB	1.49	5.72	0.03		

Column : DB-1 15m x 0.25mm x 0.1um Film
OVEN : 100°C → 10/min → 320°C (5min hold)
INLET : 250°C, 1uL/min, (50:1)
DET : FID Temp : 280°C J:280°C